WHO/UNAIDS Information Update: Consultation on Re-use of the Female Condom

Background

The burden of sexually transmitted infections, including infection with the Human Immunodeficiency Virus (HIV), the cause of the Acquired Immunodeficiency Syndrome (AIDS), continues to increase worldwide. Use of barrier methods, most notably consistent and correct use of the male latex condom, is advocated as a primary means of interrupting the spread of sexually transmitted infections, including HIV/AIDS. Because of the difficulties many women face negotiating the use of male condoms, the female condom is an important option to assist women in protecting themselves and their partners from both unwanted pregnancy and sexually transmitted infections.

The only female condom currently available is a strong, soft, transparent polyurethane sheath inserted in the vagina before sexual intercourse. This device has been approved and marketed for single-use only.

Re-use of the device by women who are unable to access a new female condom has been reported in a number of countries. WHO and UNAIDS have been requested to advise countries, programme managers and individuals who are using this female condom on the safety of re-use practices.

Consultation on Re-use of the Female Condom

WHO and UNAIDS convened a consultation on the safety and feasibility of re-use of the female condom which was held in Geneva on 5-7 June 2000. The consultation brought together experts in microbiology, sexually transmitted infections, condom production and quality assurance testing, and programmatic issues. The primary objective of this meeting was to evaluate data relevant to the safety and feasibility of re-use of the female condom, considering both the structural integrity (i.e., the ability of the condom to withstand washing and re-use without breaking or developing holes) and the potential risks of infection related to re-use. Participants were also asked to consider what policy recommendations and programme guidance, if any, could be made at present.

The consultation recognized the urgent need for risk-reduction strategies for women with limited resources who may be at risk for sexually transmitted infections including HIV. While use of a new male or female condom is a key prevention strategy, it is recognised that situations may exist when individuals are unable to use a new condom. The alternative to re-use for some may be unprotected intercourse. Re-use of the female condom is likely to occur in situations where women and men may be at high risk of sexually transmitted infections, and thus women or their partners could be at risk for exposure to pathogens from prior acts of intercourse, either during washing or subsequent re-use of the female condom.

Available Evidence and Unresolved Questions

The consultation reviewed relevant data, including the two sets of studies which have been conducted to date on re-use of the female condom. These studies investigated the structural integrity and microbial retention of female condoms which had been used, washed with soap and water and, in one study, re-used.

There is currently insufficient evidence available to determine whether a broad range of sexually transmitted pathogens, including HIV, can be inactivated and safely removed with a soap and water wash alone. Experts in microbiology were of the opinion that washing with soap and water alone could present potential risks to women during washing and/or to them or their partner during subsequent use.

While disinfection of the female condom has not been studied, it was agreed that standard disinfection procedures (e.g., soaking in a bleach solution), followed by washing with soap and water and drying, would be likely to inactivate and remove sexually transmitted pathogens from the device. However, concerns remain that disinfecting condoms may adversely affect their structural integrity.

The available evidence suggests that the structural integrity of the female condom can withstand several washes in soap and water, drying, relubrication and re-use. However, the studies also suggest that such condoms may be more likely to have holes than new condoms.

Normal vaginal flora provide important natural protection against infection. Disruption to normal vaginal flora can increase the risk for acquisition of sexually transmitted infections, including HIV. Available data indicate that use of new female condoms does not lead to changes in the normal vaginal flora. However, there are no data concerning the effect on normal vaginal flora of any residuals from disinfecting or washing with soap, or damage or contamination resulting from storing or relubricating.

Conclusions

The consultation emphasized that, given the available data and remaining gaps in knowledge, the use of a new male or female condom for every act of intercourse will continue to be recommended. However, the consultation recognized the urgent need for guidance to women or couples who are re-using female condoms and potentially placing themselves and their partners at higher risk of pregnancy and/or infection.

The consultation concluded that currently available evidence was not conclusive. Therefore, re-use of the female condom is not recommended. A draft protocol for disinfection, washing, drying, storage and relubrication was formulated and is currently being tested.

This protocol was based on theoretical considerations regarding infection control and the data from the two re-use studies on structural integrity. However, it is not known whether the proposed protocol is safe and effective in eliminating micro-organisms while maintaining the structural integrity of the female condom. Research to evaluate this protocol has already commenced with funding from WHO and findings from these studies are expected in the near future. When these results are available, WHO and UNAIDS will provide further guidance on the safety of re-use of the female condom.